MEDICAL DEVICE INTRODUCER

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to Provisional Application No. 60/195,663, filed April 7, 2000.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to medical devices. Specifically, the invention relates to inserting medical devices into a patient where the medical devices may be used in conjunction with magnetic resonance imaging.

Background of the Invention

An introducer is a secondary medical device that may be used in a surgical procedure to move a primary medical device into the patient. The introducer may be attached to a third device called a trajectory guide that positions the introducer in the direction of the area to be explored in the patient. The primary medical device may include, but is not limited to: a catheter with drug delivery capability; a tissue removal instrument such as a laser; an instrument for attaching an electrode; etc.

The alignment of an introducer may be controlled relative to the patient by the trajectory guide. Movement of the primary medical device relative to the patient is restricted once the introducer has been aligned. A translation range of motion of the introducer in operation is generally fixed in two coordinate axes, and limited to linear motion along one axis, into the patient. The introducer controls the linear motion along this single axis.

An introducer is used primarily in procedures where precise location of the primary medical device is critical, for example, brain surgery. Different variations of introducers are currently being used for procedures such as neurosurgery.

Typically, the patient is prepared by first fixing the patient in a location on an operating table surface. Conventionally, the skull of the patient is fixed to the table in

order to keep the brain located relative to the operating table surface. A trajectory guide is then conventionally mounted to a fixture on the operating table. The patient may then be operated on directly, or the patient may be positioned in a magnetic resonance imaging (MRI) station such as a long bore MR scanner. An MR tube is used in cases where a focused area of the brain is to be imaged during the surgery. Next an opening in the skull is made, and the trajectory guide is aligned with the area of the brain to be explored.

Using one prior variation, the introducer is then attached to the trajectory guide, and the desired primary medical device is attached to the introducer. The first variation introducer includes a stepper motor, controlled by a computer, that drives the primary medical device into the patient. However, the stepper motor variation is relatively heavy and expensive. The weight of the unit requires a substantial support frame attached to the operating table to ensure that this introducer does not move during the procedure. Additionally, time consumed in re-sterilization between procedures means that this variation is frequently not available for use. The stepper motor variation is also not compatible with an MR tube environment.

A method that can be used in conjunction with an MR tube environment is "free-hand" introduction. Unfortunately, with this method, the surgeon cannot view the patient and the primary medical device in "real time." This is because the surgeon cannot simultaneously both view the MR display screen and operate the introducer. In real time imaging, the patient is inside an MR scanner, such as a long bore MR scanner. In order to view the MR image of the patient, the surgeon must be outside the long bore MR scanner, looking at the display screen. At the same time, in order to introduce the primary medical device, the surgeon must be near the patient, and not in a position to adequately view the display screen.

A variation of introducer that has been used to overcome the real time imaging insertion problem uses hydraulic lines to remotely control the introducer. The setup of the patient in this variation is the same, but the introducer further includes a remote actuation unit and hydraulic lines that lead from the remote actuation unit to the introducer. With the hydraulic variation, the surgeon can view the patient within the long bore MR tube, and at the same time the surgeon can actuate the introducer to move the primary medical device into the patient.

A significant problem with the hydraulic introducer is that this device is expensive and contains many complicated components that must be inspected and maintained. Another problem with the hydraulic variation is that the hydraulic fluid used to actuate this variation of remote introducer must be sealed and sterile or it must be re-sterilized after each surgical procedure.

What is needed is an inexpensive, lightweight introducer that can be used once and disposed of. What is also needed is an inexpensive introducer device that requires a minimal number of components to maintain, and requires minimal patient set up equipment to further minimize costs. What is also needed is an inexpensive remote introducer that allows the surgeon to both view the patient in real time, and actuate the remote introducer to move the primary medical device into the patient.

SUMMARY OF THE INVENTION

The invention includes an introducer that is inexpensive to manufacture with a minimum number of components. The introducer includes a guide unit and a holder assembly that moves along the guide unit. The holder assembly is capable of receiving a primary medical device and introducing the primary medical device into a patient. The invention includes an advancer that may be remote from the introducer. In the case of a remote advancer, the advancer may be coupled to the introducer by a cable system.

The invention may include a position scale that is located on the advancer, or it may include a position sensor that is mounted locally on the introducer. The position sensor may include a potentiometer or an encoder or similar device. The invention may also include a centering plate that aids in alignment of the primary medical device being used.

The advancer may include a thumb wheel that advances the primary medical device into the patient by rotating the thumb wheel. The advancer may further include a locking mechanism that fixes the thumb wheel in place when not in use. The locking mechanism may operate in either a "free wheeling" mode or a "discrete step" mode. The advancer may also include an indicator scale that shows the depth of the primary medical device in the patient.

The invention may include an introduction system that includes an introducer, a trajectory guide, and a primary medical device. The introduction system may also include a frameless reference system.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 shows a perspective view of an introducer device according to the invention.

Figure 2 shows an exploded view of the introducer device of Figure 1.

Figure 3 shows a perspective view of a remote introducer including an advancer according to the invention.

Figure 4 shows an exploded view of the advancer from Figure 3.

Figure 5a shows a perspective view of a trajectory guide.

Figure 5b shows a perspective view of a trajectory guide with an alignment tube and locking ring.

Figure 6 shows a perspective view of an introduction system according to the invention.

Figure 7 shows an introduction system including a frameless reference system.

Figure 8 shows a perspective, partially exploded view of a calibrated introducer device.

Figure 9 shows an exploded view of a non-remote introducer device according to the invention.

DESCRIPTION OF THE INVENTION

An introducer is described below that is lightweight, inexpensive to manufacture, and is comprised of a minimum number of moving parts. As a result it may be used disposably and will not require re-sterilization. One embodiment is also a remote introducer that may be actuated from a remote location while a patient is inside a device such as a long bore MR tube. Other embodiments include elements that reference the relative position of a primary medical device being inserted into a patient. Still another embodiment includes an introducer that is mounted directly to a patient instead of mounting to a fixture on a table surface.

Figures 1 and 2 show an introducer 100 according to the invention. A first cable housing 110 and a second cable housing 120 are also shown in Figure 1 with a cable 130 running through both the first cable housing 110 and the second cable housing 120. When designed for MR imaging use, all materials used in this embodiment must be compatible with the MR tube environment. Specifically the materials used with MR imaging are non-magnetic. Some metals may be used, such as titanium or copper, or various polymer materials may be used.

Figure 2 shows an exploded view of the introducer 100. The introducer includes a slide tower 210, the slide tower having an attachment end 211 and a cable guide end 212. The slide tower 210 is attached at the attachment end 211 to a body 240. The body contains a first body interface 242 that accepts the first cable housing 110 and a second body interface 243 that accepts the second cable housing 120. In this embodiment, the first cable housing is routed into the body 240 at the first body interface 242, and out of the body at a third body interface 244. The first cable housing 110 then routes along the slide tower 210 and butts up against the cable guide end 212. The second cable housing 120 routes partially into the body 240, and butts up against the body 240 at the second body interface 243.

A holder assembly 220 is attached to the slide tower 210, and allowed to along a sliding axis 214 between the body 240 and the cable guide end 212 of the slide tower 210 in a range of linear motion. The holder assembly 220 is comprised of a channel portion 221 that slidably engages the slide tower 210. The holder assembly also comprises a primary device holder portion 222 that comprises a holder hole 223 through its center. The holder hole 223 aligns with the sliding axis 214 of the slide tower 210. A set screw 230 screws into the holder assembly 220 in a threaded side hole 224. The set screw is comprised of a knob portion 232 and a threaded portion 231.

The cable 130 routes in to the introducer 100 through the first cable housing 110 passing through the body 240 at the first body interface 242 and out the third body interface 244. When the cable reaches the cable guide end 212 of the slide tower 210 it exits the first cable housing 110 and the bare cable 130 routes over the cable guide end along a groove 213 then travels back down the slide tower 210. The bare cable 130 is attached to the holder assembly 220 then continues down the slide tower 210 where it

enters a fourth body interface 245. The cable 130 then enters the second cable housing 120 at the second body interface 243, and exits the introducer 100, While a push-pull cable configuration is described in this embodiment, other cable configurations are possible within the scope of the invention. For instance, a rotating cable similar to a speedometer cable could be used to actuate a mechanism such as a worm gear drive.

The body 240 further includes a guide hole 241 that passes through the body 240 parallel to the sliding axis 214. An attachment pin 260 passes through the body 240 and is used to secure the introducer 100 to a trajectory guide that will be described later. A centering plate 250 is also included with the introducer 100, and is slidably attached to the body 240 by a groove 246. The centering plate defines an opening 253. The opening 253 includes a first wall 251 and a second wall 252 that are at an angle to each other.

Figure 3 shows a complete remote introducer 300 according to the invention. The remote introducer includes an introducer 100 and a remote advancer 310. The remote advancer 310 is coupled to the introducer 100 by the first cable housing 110 and the second cable housing 120 with the cable 130 running through the introducer as described above.

Several configurations of remote advancers are possible within the scope of the invention. One embodiment could include a crank operated advancer similar to a fishing reel. Another embodiment could include both a coarse adjustment advancer and a fine adjustment advancer. Another embodiment could include a ratcheting mechanism that is advanced by a trigger. One skilled in the art will recognize that potential configurations such as these may be interchanged and still fall within the scope of the invention. In the following embodiment, the advancer includes a thumb wheel.

Figure 4 shows an exploded view of the advancer 310. A first grip portion 410 and a second grip portion 420 are attached together to form a grip. A thumb wheel 430 is located between the first grip portion 410 and the second grip portion 420 and is allowed to rotate. A cable stop 460 is located next to the thumb wheel 430. The cable stop comprises a threaded adjusting hole 465, a first cable hole 466 and a second cable hole 467. The first threaded adjusting hole 465 accepts an adjusting screw 461. The cable stop further includes a first threaded hole 468 and a second threaded hole 469 for accepting a first set screw 463 and a second set screw 464.

The first cable housing 110 comes from the introducer 100 and butts against the first cable hole 466. Likewise, the second cable housing comes from the introducer 100 and butts against the second cable hole 467. The cable 130 runs through the introducer 100 as described above, and runs through the cable stop 460 at the first and second cable holes 466 and 467. The bare cable 130 is then wrapped around a thumb wheel barrel 431 located at the center of the thumb wheel 430. The portion of the cable exiting the first cable housing 110 is wrapped around the barrel 431 in one direction, while the portion of the cable exiting the second cable housing 120 is wrapped around the barrel 431 in an opposing direction. The cable 130 is fastened to the thumb wheel 430 after being wrapped around the barrel 431. The cable tension is adjusted by tightening the adjusting screw 461 against a screw stop 421.

The thumb wheel 430 also contains an array of teeth 432 on its outer edge. An engager 451 meshes with the array of teeth 432 to lock rotation of the thumb wheel 430 when not in operation. A locking trigger 450 controls the engager 451. Both the locking trigger and the engager are biased in a resting position by an elastic band (not shown) The engager is biased against the array of teeth 432 which keeps the advancer 310 in a "normally locked" state.

An indicator molding 440 is also included with the advancer 310. It is attached to the advancer 310 by and indicator screw 441 that passes through the indicator molding 440, through an o-ring 442, and through a bushing 443. The indicator molding 440 includes an array of markings 444 that may be aligned with a reference mark 445 on the first grip portion 410.

The remote introducer 300 from Figure 3 may be used as part of an introduction system as shown in Figure 6. The introduction system includes a trajectory guide 500 as shown in Figures 5a and 5b. The trajectory guide 500 includes a guide base 540 with a number of screw holes at the outer edges of the guide base and a socket 545 in the center of the guide base 540. A stem 520 is attached to the guide base by a ball 510 that fits into the socket 545 to form a ball and socket joint. Figure 5b shows an alignment tube 550 that is inserted in the stem 520 only during alignment, then it is removed. A lockring 560 is also shown that fixes the alignment of the stem in a desired position.

The introduction system shown in Figure 6 includes a trajectory guide 500, an introducer 100 and a primary medical device 600. The introducer shown in Figure 6 is a remote introducer 300, however, the advancer 310 is not shown. The primary medical device 600 includes a distal end 610 and a proximal end 620. The active end of the primary medical device is the distal end 610, which may be an MR microcoil, a drug delivery system, an electrode, etc.

One of ordinary skill in the art will recognize that although the invention described is designed to be compatible with an MR environment, the invention is also capable of being used without an MR imaging system. Certain aspects of the invention such as cable and mounting screw materials only need to be MR compatible if the invention is used in an MR environment. All MR compatible materials are capable of being used outside an MR environment.

In magnetic resonance imaging operation, the guide base 540 of the trajectory guide 500 is attached to the patient, for example to the patient's skull. The guide base 540 is attached using screws made from, for example, titanium metal. The alignment tube 550 is inserted into the stem 520, and the patient is placed in an MR tube. The alignment tube 550 is visible in the MR scan, along with the patient's brain. The stem 520 is aligned by using the alignment tube 550, and once it is aligned with an area of interest in the patient's brain, the stem 520 is locked in place using the locking ring 560 and the alignment tube 550 is removed.

The introducer 100 is then attached to the stem 520 and the primary medical device 600 is threaded through the holder assembly hole 223, through the centering plate 250, and into the guide hole 241 of the body 240. Once the primary medical device 600 is threaded into place, it is clamped in the holder assembly using the set screw 230. Next, the centering plate 250 is moved in its groove 246 towards the slide tower 210, and into contact with the primary medical device 600. The first wall 251 and the second wall 252 of the opening 253 contact the primary medical device 600 at two tangent points, and the walls 251 and 252 push the primary medical device 600 into the center of the guide hole 241 in the body 240. Then, a marking in the array of markings 444 on the indicator molding 440 is aligned with the reference marking 445 on the advancer 310. The

indicator molding now shows a reference point of where motion of the primary medical device began.

While monitoring the patient in real time in the MR tube, the surgeon first unlocks the advancer by depressing the locking trigger 450. The primary medical device is then advanced into the patient by rotating the thumb wheel 430. The indicator molding 440 rotates with the thumb wheel 430 and shows the surgeon how far the primary medical device has moved into the patient. The position of the primary medical device can also be viewed using the MR image generated by the MR tube.

When the locking trigger 450 is fully depressed and held down, the advancer is in a "free wheeling" mode, and the thumb wheel can be moved as little or as much as is desired. If the locking trigger is depressed ½ way down, the advancer is in a "discrete step" mode. In the discrete step mode, the thumb wheel will click as each tooth of the array 432 passes the engager 451. Each discrete step is equal to ½ millimeter of travel of the primary medical device. It should be noted, however, that the distance traveled in a discrete step could be any of a number of distances.

A further embodiment of the introduction system is shown in Figure 7. The remote introducer 300 shown in the figure may include a first frameless reference attachment 710. The first frameless reference attachment is attached to the holder assembly 220 of the introducer 100. The first frameless reference attachment includes a number of balls 711 attached to a number of arms 712. Each ball 711 is reflective to infrared (IR) light. A second frameless reference attachment 720 is attached to a table 700 that the patient is attached to.

In place of the number of balls, one or more non-magnetic coils may be attached to the first and second frameless reference attachments 710 and 720. The coils are electrically influenced by the magnetic field in the MR tube and each coil defines a line in three-dimensional space. Because a coil defines a line in space as opposed to a point defined by a ball, only two coils are necessary to define a three-dimensional reference frame.

In operation, the surgeon may use the first and second frameless reference attachments 710 and 720 with an IR camera and IR light source (not shown). The patient is attached to the table 700, and the position of the table is referenced by the second

frameless reference attachment 720. IR light from the IR light source is reflected off of the balls 711 and detected by the IR camera. The position of the primary medical device is known in relation to the patient by comparing the location of the first frameless reference attachment 710 to the location of the second frameless reference attachment 720.

In another embodiment, the balls 711 may include IR light generating LED devices. In this embodiment, only the IR sensitive camera is needed to detect the location of the first and second frameless reference attachments 710 and 720.

If the non-magnetic coils are used, no IR generating or sensing equipment is necessary. Only a user interface device is needed that monitors the electrical characteristics of the coils and translates the electrical characteristics into a three-dimensional reference frame.

In a further embodiment, shown in Figure 8, a local position sensor 800 is attached to the introducer 100. In the embodiment shown, the local position sensor comprises a potentiometer, however, it should be recognized that a linear encoder or similar device could be used. A first clamp 810 and a second clamp 820 are attached to the holder assembly 220. The first and second clamps 810 and 820 are then attached to a sensor slide 840 and allowed to move up and down the sensor slide 840 as the holder assembly 220 moves up and down the slide tower 210. The potentiometer consists of a first electrode 851 that is attached to the clamps 810 and 820, and a second electrode 852 that is fixed on the back of the sensor slide 840. An electrical relationship of the two electrodes 851 and 852 changes as the holder assembly moves up and down in its range of motion, and this electrical relationship is translated into an accurate position of the holder assembly. The local position sensor 800 is used as a more accurate indicator than the indicator molding 440. The accuracy of the indicator molding 440 is affected by factors such as cable stretch that the local position sensor 800 is not affected by.

In a further embodiment, shown in Figure 9, a local introducer is shown. The local introducer is comprised of a base 940 that may be attached to a trajectory guide 500 by using a base set screw 945. A slide tower 970 is attached to the base 940. The slide tower 970 includes a holder assembly groove 974 and an advancer wheel groove 972. A holder assembly 920 slides in the holder assembly groove 974, and the position of the

holder assembly is fixed by a threaded bar 910. A set screw 930 is used to clamp a primary medical device in place within the holder assembly 920. An advancer wheel 950 is located in the advancer wheel groove 972, and attached to an encoder axle 962. The encoder axle is also attached to an encoder 960 and a first drive gear 965. A second drive gear 915 connects the threaded bar 910 with the encoder axle 962.

In operation, the advancer wheel 950 is rotated a desired amount. Rotation of the advancer wheel drives the encoder 960, and the first drive gear 965. The first drive gear 965 in turn drives the second drive gear 915 which drives the threaded bar 910. The threaded bar 910 moves the holder assembly 920 along the holder assembly groove 974. The encoder is calibrated to deliver an electrical signal to a remote display (not shown) that corresponds to a holder assembly location.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those skilled in the art that any arrangement which is calculated to achieve the same purpose may be substituted for the specific embodiment shown. This application is intended to cover any adaptations of variations of the present invention. It is to be understood that the above description is intended to be illustrative, and not restrictive. The scope of the invention includes any other applications in which the above structures and fabrication methods are used. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.